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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/082,112
Filing Date: May 20, 1998
Appellant(s): MENDOZA, ALBERTO L.

Ian C. McLeod
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/14/2006 appealing from the Office action mailed 6/14/2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

A decision by the Board in Appeal No. 2003-1819 for the present Application No. 09/082,112 is contained in the brief and is provided herein.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner.

Specification Objection

The objection to the amendment filed 10/8/1999 under 35 U.S.C. 132(a) because it introduces new matter into the disclosure, is withdrawn upon reconsideration. Based on MPEP 2406.02 and on the evidence that the strain deposited with the ATCC as ATCC strain 58643 is the same strain as the strain deposited with the ATCC as ATCC strain 74446, the objection is withdrawn.

35 USC § 112

The rejection of claim 21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn upon reconsideration. Based on MPEP 2406.02 and on the evidence that the strain deposited with the ATCC as ATCC strain 58643 is the same strain as the strain deposited with the ATCC as ATCC strain 74446, the rejection is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Mendoza et al. (92a)(Mycopathologia 119:89-95, 1992)

Mendoza et al. (92b)(J. Clinical Microbiol, 30:2980-2983, 1992)

Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995)

Mendoza et al. (J. Mycol. Med., 6:151-164, 1996)

Blanch et al. (Biochemical Engineering, Marcel Dekker, Inc., 1996)

Amicon 1993 catalog

Fisher 1995 catalog

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 USC § 103

Claims 18, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992) in view of Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog for the reasons set forth in the office action filed 12/21/2005.

The instant claims are drawn to a method for treatment of an infection caused by *Pythium insidiosum* in a mammal which comprises providing an injectable vaccine comprising:

1. mixed intracellular proteins, which consist essentially of proteins removed from disrupted cells of *Pythium insidiosum* separated from the culture medium; and
2. mixed extracellular proteins, which consist essentially of proteins removed from the culture medium separated from the cells of the *Pythium insidiosum*;

wherein the admixture of proteins has been precipitated from the culture medium with acetone and admixed with water and then has been dialyzed to remove low molecular weight components less than 10,000 MW (claim 18). Further limitations include the method of claim 18 where the cells have been disrupted by sonication (claim 20), where the *Pythium insidiosum* is deposited as ATCC 74446 (claim 21), and where the culture medium is Sabouraud's dextrose broth (claim 22).

Mendoza *et al.* (92a) teach subcutaneous administration of two vaccines for pythiosis, the Cell Mass Vaccine (CMV), and the Soluble Concentrated Antigen Vaccine (SCAV) to mammals. The CMV consists of mixed intracellular antigens of *P. insidiosum* obtained by culturing *P. insidiosum* (ATCC 58643) in Sabouraud's dextrose broth. The cells were removed from the culture medium and disrupted by homogenization to provide the antigens for the vaccine (p. 90, col. 2). The SCAV consists of extracellular proteins obtained by culturing *P. insidiosum* (ATCC 58643) in Sabouraud's dextrose broth. The extracellular antigens were concentrated with a stir cell and precipitated with acetone (p. 91, col. 2 and p.92 col. 1). Mendoza *et al.* (92a) teach that both vaccines were successful in curing cases of pythiosis in

horses (p. 91, col. 2, paragraph 2). Mendoza *et al.* (92a) further teaches that the etiological agent of pythiosis in horses, cattle, dogs, cats, and humans is *Pythium isidiosum*, and that nine strains isolated from humans, horses, and dogs with the disease were all the same species (p. 89, paragraph 1).

Mendoza *et al.* (92a) differs from the instant invention in that it does not teach that the intracellular proteins are separated from the disrupted cells in the CMV or the use of sonication to disrupt the cells. Mendoza *et al.* (92a) further does not teach the use of dialysis to remove components less than 10,000 MW or a vaccine that is a mixture of the intracellular and extracellular proteins.

Mendoza *et al.* (92b) teach alternative methods to produce intracellular and extracellular protein pythiosis vaccines. The composition containing the intracellular proteins was produced by culturing *P. insidiosum*, killing the cells with Methiolate (thimersol), sonicating the cells to disrupt them and release intracellular proteins, then separated from the cell debris by centrifugation (p. 2981, col. 1, paragraph 1). An alternative method to produce a composition containing extracellular proteins is also taught. Cultures were killed with Merthiolate (thimersol), filtered to remove cells, and a stir cell with PM-10 membrane (Amicon) was used to concentrate the antigen (and remove low molecular weight components)(p. 2981, col. 1, paragraph 2). They also teach the important antigens found in the CMV vaccine and disclose that in addition to three immunodominant proteins (32K, 30K, and 28K) there are at least 20 antigens found in the intracellular proteins of *Pythium isidiosum* that are reactive in horse sera (p. 2981, col. 2, paragraph 3) and suggest that vaccines should include the three immunodominant proteins (p. 2982, col. 2, paragraph 3). Mendoza *et al.* (92b) also teach that five strains of *Pythium isidiosum* all had similar intracellular protein profiles.

Mendoza (95) teaches a vaccine that combined extracellular pythium antigens and the three immunodominant intracellular proteins of Mendoza (92b) and that said vaccine had an enhanced therapeutic effect on horses (see abstract). Mendoza (95) further teaches that hyphal antigens may contain products that are directly involved in the enhancement of the immunological response to vaccination (see abstract).

The Amicon 1993 catalog teaches that a PM10 membrane will retain molecules larger than 10,000 MW (p. 35).

The Fisher 1995 catalog teaches dialysis membranes which will retain molecules larger than 10,000 MW (p. 56).

As to claims 18, 20-22, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to administer, to mammals, a pythiosis vaccine comprising a mixture of mixed intracellular proteins (especially including the three immunodominant proteins of Mendoza (92b)) and mixed extracellular proteins because Mendoza (95) teaches that a vaccine comprising a mixture of three immunodominant intracellular proteins and extracellular proteins was more successful in curing horses than either the CMV or SCAV vaccines, and because Mendoza (92b) teaches that there are at least 20 reactive antigens found in the intracellular proteins of *Pythium isidiosum* that might be useful in immunotherapy. It would also have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to use the method obtain the intracellular antigens by culturing *P. insidiosum*, killing the cells with Methiolate (thimersol), sonicating the cells to disrupt them and release intracellular proteins, then separated from the cell debris by centrifugation because it would be easier to obtain the intracellular proteins this way, rather than using electrophoresis to obtain only the three immunodominant proteins. The ordinary artisan would also have been motivated to use dialysis instead of a stir-cell with a PM10 membrane because dialysis is significantly cheaper and provides for large batches. Further, as taught by the Amicon and Fisher catalogs, the removal of small molecules of less than 10,000 MW by the PM10 membrane and the dialysis membrane is functionally equivalent.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992), Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog as applied to claims 18, 20-22 above, and further in view of Mendoza *et al.* (J. Mycol. Med., 6:151-164, 1996) for the reasons set forth in the office action filed 12/21/2005.

The instant claims are drawn to a method for treatment of an infection caused by *Pythium insidiosum* in humans which comprises providing an injectable vaccine comprising:

1. mixed intracellular proteins, which consist essentially of proteins removed from disrupted cells of *Pythium insidiosum* separated from the culture medium; and
2. mixed extracellular proteins, which consist essentially of proteins removed from the culture medium separated from the cells of the *Pythium insidiosum*;

wherein the admixture of proteins has been precipitated from the culture medium with acetone and admixed with water and then has been dialyzed to remove low molecular weight components less than 10,000 MW (claim 16), and wherein said vaccination is subcutaneous (claim 17).

Mendoza *et al.* (92a), Mendoza *et al.* (92b), Mendoza (95), Amicon 1993 catalog, and Fisher 1995 catalog as combined over claims 18, 20-22 is set forth *supra*. The combination as set forth *supra* does not teach the treatment of pythiosis in humans using the vaccine as set forth above.

Mendoza *et al.* (96) teach the prevalence of human pythiosis and the need for an effective treatment for humans (p. 156, col. 2 and p. 160, col. 2, paragraph 2). They also teach the benefits of vaccination using intracellular (CMV) and extracellular (SCAV) antigens from *P. insidiosum* (p. 161, Immunotherapy). Mendoza *et al.* (96) further teach similarities in *P. insidiosum* antigens detected in human and horse sera (p. 159, Immunodiffusion test).

As to claims 16-17, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of invention to use the mixed intra and extracellular vaccine combination set forth *supra* to treat humans because of the similarity in immune response in humans to that found in horses, because of the increased benefit seen by the combination in horses, and by the need for an effective treatment in humans.

Claims 19, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992), Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog as applied to claims 18, 20-22 above, and further in view of Blanch *et al.* (Biochemical Engineering, Marcel Dekker, Inc., 1996) for the reasons set forth in the office action filed 12/21/2005.

The instant claims are drawn to a method for the treatment of Pythiosis in a mammal which comprises injecting a vaccine comprising:

1. mixed intracellular proteins, which consist essentially of proteins removed from disrupted cells of *Pythium insidiosum* separated from the culture medium; and
2. mixed extracellular proteins, which consist essentially of proteins removed from the culture medium separated from the cells of the *Pythium insidiosum*;

wherein the admixture of proteins has been precipitated from the culture medium with acetone and admixed with water and then has been dialyzed to remove low molecular weight components less than 10,000 MW (claim 19); wherein the culture medium is Sabouraud's dextrose broth (claim 22); wherein the cells have been killed with thimersol (claim 23); and wherein the disrupted cells are removed from the sterile water containing the mixed intracellular proteins by centrifugation to provide the mixed intracellular proteins of (1) in the second supernatant (claim 24).

Mendoza *et al.* (92a), Mendoza *et al.* (92b), Mendoza (95), Amicon 1993 catalog, and Fisher 1995 catalog as combined over claims 18, 20-22 is set forth *supra*. The combination as set forth *supra* does not teach the use of acetone to precipitate proteins after the intracellular proteins have been mixed with the extracellular proteins.

Blanch *et al.* teach that one of the most common methods of precipitating proteins is through the addition of acetone, and that it is usually preferred over longer-chain organics (p. 491, paragraph 4 and p. 496, paragraph 2).

As to claims 19, 22-25, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of invention to use acetone to precipitate the proteins of the invention because it is standard in the art to use acetone precipitation and because Blanch *et al.* teach that one of the most common methods of precipitating proteins is through the addition of acetone.

(10) Response to Argument

A. Rejection of claims over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992) in view of Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog.

Applicant argues:

1. That, though the prior art teaches an extracellular protein vaccine (SCAV) and an intracellular protein vaccine (CMV), both vaccines were of limited value for treating horses infected greater than 0.5 months but less than 2 months and neither vaccine was effective for treating horses that had been infected for more than 2 months and that the CMV vaccine has several drawbacks in that it has a short shelf-life and causes severe inflammatory reactions.

2. That, while Mendoza 92b suggests that the 28, 30, and 32 kD proteins may be useful for diagnostic purposes and as candidates for vaccination trials, it does not actually disclose a vaccine.

3. That the claimed vaccine lacks components with a molecular weight less than 10,000 and retains the larger molecular weight components. Applicant asserts that Mendoza 92b show that at least 20 antigens from *P. insidiosum* can be found and most ranged in weight from 14,000-68,000; therefore, while the 28, 30, and 32 kD proteins were prominent, there are many other antigens in the intracellular mixture that horses will react against.

4. That one skilled in the art would expect the intracellular protein composition of Mendoza 92b to have a short shelf-life and that, because it contained numerous intracellular protein antigens, one would conclude that a horse would produce a prominent inflammatory response at the site of inoculation, as taught by Mendoza 92a. Applicant asserts that, since these are undesirable properties in a vaccine, one would not be motivated to create a vaccine containing all of the soluble intracellular proteins greater than 10,000 MW and one would not be motivated to add any additional proteins beyond the three prominent proteins found in the vaccine of Mendoza 95 to avoid the prominent inflammatory response.

5. That applicant's have claimed a method providing a vaccine with the enhanced curative properties of the vaccine of Mendoza 95 (properties that are lacking in the SCAV and CMV), while not having the undesirable property of causing inflammation as seen with the CMV vaccine. Applicant asserts that mild inflammatory reactions are unexpected results, considering the teachings of Mendoza 92a. Applicant cites Mendoza 92a who showed that half of the horses vaccinated with CMV developed violent reactions and states that, while it is true that Mendoza 92a teaches that the reaction was a function of the amount of vaccine inoculated, a person of skill in the art would not be motivated to decrease the amount of vaccine when Mendoza 92a teaches that the CMV is not effective for treatment of chronic cases.

6. That one would not be motivated to provide the claimed vaccine because the cited references suggest that the claimed vaccine would have undesirable properties. Applicant asserts that the references "teach away from a vaccine having all of the larger molecular weight components present in the vaccine because of these expected properties." Applicant argues that it would be unexpected that such a vaccine would not cause severe inflammation and sterile abscesses at the injection cite, based on the teachings of the cited references and that, while Mendoza 95 teaches that adding the three prominent intracellular proteins improved the SCAV vaccine, it does not show or suggest that the vaccine of the claimed method could also cure chronic pythiosis without causing the inflammation problem associated with the CMV vaccine.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, it is the combination of references which renders the instantly claimed invention obvious, not the disclosure of either the CMV or SCAV vaccines alone. Whether these properties show unexpected results will be dealt with in the following paragraphs.

It is important to note, however, that applicant's assertion that the CMV vaccine causes severe inflammatory reactions ignores the teachings of Mendoza 92a, who showed that the inflammatory response was a function of the amount of vaccine inoculated. The authors were able to obtain a suitable response without severe inflammatory reactions using both types of vaccines (see page 92, column 2, paragraph 3). Therefore, by simply optimizing the amount of antigen, the "problem" of severe inflammatory reactions was resolved in the prior art.

Regarding argument 2, Mendoza (92b) specifically suggests the use of the three immunodominant antigens as vaccines (see page 2982, column 2, paragraph 3).

Regarding argument 3, applicant correctly characterizes the molecular weight of the protein components in *P. insidiosum* and correctly points out that there are antigens in addition to the 28, 30, and 32 kD proteins to which horses will react. It is noted that none of these antigens were less then 10,000 molecular weight, suggesting that one would have no reason to include the lower weight antigens.

Regarding argument 4, the shelf-life of the CMV vaccine or even of the claimed vaccine is not at issue. There is no mention made of shelf-life in the claims, and applicant has provided no evidence that the claimed vaccine has a shelf-life that is any different than the CMV vaccine or the combination vaccine disclosed by Mendoza 95. With regard to the "undesirable property" of producing a prominent inflammatory reaction, as discussed above, the issue of inflammatory responses was resolved in Mendoza 92a by adjusting the dosage of the vaccine. In addition, as discussed in the previous decision by the Board, the combination of the CMV and SCAV would provide the required constituents (i.e., the immunodominant 28, 30, and 32 kD proteins) but would be easier in preparation than providing only the isolated immunodominant proteins

because there would be no need for the additional preparative steps of isolating said immunodominant proteins.

Regarding argument 5, as stated above, mild inflammatory reactions are not an unexpected result, as Mendoza 92a specifically dealt with this issue by adjusting the dosage of the vaccine. Both the CMV and SCAV vaccines cured infections "without the development of severe inflammatory reactions" (see page 92, final paragraph). Applicant correctly states that CMV was not effective in curing chronic cases (i.e., 2 months or more in duration); however, this ignores the teachings of Mendoza 95, who showed that adding intracellular proteins to the SCAV vaccine led to enhance curative properties, including the cure of chronic cases. Therefore, knowing that the addition of intracellular proteins to the extracellular proteins of the SCAV vaccine, one would have expected enhanced curative properties, and since it had already been shown how to avoid severe inflammatory responses, one would not have expected these to be a problem in the combination vaccine (it is also noted that severe inflammatory responses were not noted as being produced by the combination vaccine in Mendoza 95).

Regarding argument 6, as stated above, no undesirable properties have been shown to be an issue in either the combination vaccine containing intracellular and extracellular proteins or in either the CMV or SCAV vaccines. The enhanced curative properties that result from addition of the three immunodominant intracellular proteins to the extracellular protein vaccine were already shown in the art and therefore would have been expected in a combination comprising additional intracellular proteins.

B. Rejection of claims over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992) in view of Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog, further in view of Mendoza *et al.* (J. Mycol. Med., 6:151-164, 1996).

Applicant argues:

1. That Mendoza 96 does not show or suggest that "a vaccine with soluble intracellular proteins as prepared in the claimed method would not have an inflammation problem associated with the CMS [sic] vaccine." Applicant asserts that it would not be obvious to one of skill in the art that such a vaccine would be safe enough for treating humans. Applicant further asserts that Mendoza 92a showed that the CMV vaccine caused prominent inflammatory responses in half of the horses vaccinated; therefore, one would not have been motivated to provide the claimed vaccine to human patients.

2. That the present invention has been shown to be a good choice to treat human pythiosis and that nothing in the cited references would suggest that human treatment would be possible.

3. That references must be viewed without the benefit of impermissible hindsight.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, as discussed above, Mendoza 92a resolved the issue with inflammatory responses at the injection site. Therefore, there would have been no expectation of unsuitable responses in humans. In addition, Mendoza 96, disclosed that a modification of previous vaccines led to an increase in the number of cured cases, and that 50% of horses with chronic pythiosis (>2 months) responded to this modified vaccine, and that the horses that had

not previously responded did not develop swellings at the vaccination site (see page 161, paragraph bridging columns 1-2).

Regarding argument 2, Mendoza 96 teach similarities in *P. insidiosum* antigens detected in human and horse sera (p. 159, Immunodiffusion test). Knowing the similarity in serum response in horses and humans shown by Mendoza 96 and the similarity in human and animal pythiosis infections, one would have expected the same beneficial response in humans as in horses.

Regarding argument 3, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Aside from simply stating that impermissible hindsight is improper, applicant has not pointed out how the rejection uses such hindsight. All of the teachings and suggestions referred to by the examiner can be found in the prior art, thereby using only knowledge which was within the level of ordinary skill at the time the invention was made.

C. Rejection of claims over Mendoza *et al.* (92a)(Mycopathologia 119:89-95, 1992) in view of Mendoza *et al.* (92b)(J. Clinical Microbiol, 30:2980-2983, 1992), Mendoza (3rd NIAID Workshop in Med. Mycol. Series Abstracts, 1995), Amicon 1993 catalog, and Fisher 1995 catalog, further in view of Blanch *et al.* (Biochemical Engineering, Marcel Dekker, Inc., 1996).

Applicant argues:

1. That nothing in Blanch would motivate one to provide a vaccine as in the claimed methods because Blanch does not show or suggest a vaccine having the enhanced curative properties of the vaccine of Mendoza 95 (properties that are lacking in the SCAV and CMV), while not having the undesirable property of causing inflammation as seen with the CMV vaccine.

Applicant's arguments have been fully considered and deemed non-persuasive.

As stated above, mild inflammatory reactions are not an unexpected result, as Mendoza 92a specifically dealt with this issue by adjusting the dosage of the vaccine. Both the CMV and SCAV vaccines cured infections "without the development of severe inflammatory reactions" (see page 92, final paragraph). Applicant correctly states that CMV was not effective in curing chronic cases (i.e., 2 months or more in duration); however, this ignores the teachings of Mendoza 95, who showed that adding intracellular proteins to the SCAV vaccine led to enhance curative properties, including the cure of chronic cases. Therefore, knowing that the addition of intracellular proteins to the extracellular proteins of the SCAV vaccine, one would have expected enhanced curative properties, and since it had already been shown how to avoid severe inflammatory responses, one would not have expected these to be a problem in the combination vaccine (it is also noted that severe inflammatory responses were not noted as being produced by the combination vaccine in Mendoza 95).

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian J Gangle/

Examiner, Art Unit 1645

Conferees:

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649